K052614

SEP 2 8 2005

VIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Arthrex Low Profile Plate and Screw System

NAME OF SPONSOR:

Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

510(K) CONTACT:

Sally Foust, RAC
Regulatory Affairs Project Manager
Telephone: (239) 643-5553 extension 1251
FAX: (239) 598-5539

TRADE NAME:
Arthrex Low Profile Plate and Screw System

COMMON NAME:
Plate, fixation, bone
Screw, fixation, bone

CLASSIFICATION / PRODUCT CODE

21 CFR 888.3030 / HRS
Single/multiple component metallic bone fixation appliances and accessories
21 CFR 888.3040 / HWC
Fastener, Fixation, Nondegradable, Soft Tissue
Smooth or threaded metallic bone fixation fastener

PREDICATE DEVICES:
K040907 Arthrex Small Fragment Plates and Screws

DEVICE DESCRIPTION AND INTENDED USE:
The Arthrex Low Profile Plate and Screw System consists of plates and screws. The plate is an L-shaped plate with four holes for insertion of screws for fixation. The plate is available in opening and closing wedge design, in various lengths, in both left and right configurations. The Arthrex screw is a cortical, headed, self-tapping screw available in one diameter, in numerous length options.

The Arthrex Low Profile Plate and Screw System is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand, and wrist, such as opening wedge osteotomies for Hallux Valgus.

SUBSTANTIAL EQUIVALENCE SUMMARY
The Arthrex Low Profile Plate and Screw System is substantially equivalent to the predicate device where basic features and intended uses are the same. Any differences between the Low Profile Plate and Screw System and the predicate device are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the Low Profile Plate and Screw System is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2005

Ms. Sally Foust, RAC
Regulatory Affairs Project Manager
Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K052614
Trade/Device Name: Arthrex Low Profile Plate and Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: September 21, 2005
Received: September 23, 2005

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. INDICATIONS FOR USE FORM

510(k) Number (if known): _____

Device Name: Arthrex Low Profile Plate and Screw System

Indications for Use:

The Arthrex Low Profile Plate and Screw System is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand, and wrist, such as opening wedge osteotomies of Hallux Valgus.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052614